DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO ATTENTION OF

MCMR-ZA

08 AUG 1997

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Investigational Medical Product Clinical Study Compliance with Food and Drug Administration Regulations

1. It is imperative that all clinical investigations conducted or funded by this Command involving Food and Drug Administration (FDA) regulated medical products are conducted in accordance with all applicable Army, Department of Defense, Federal, and FDA regulations. All Investigational New Drug (IND) and Investigational New Device (IDE) clinical studies sponsored by The Surgeon General (TSG) or by investigators within this Command which do not have appropriate administrative policies, procedures, and resources applied to achieve administrative and procedural compliance with FDA regulations will be designated for clinical hold and/or closure until corrective actions are taken.

2. The Deputy Chief of Staff for Regulatory Compliance and Quality (DCSRCQ) is directed to identify all clinical studies conducted under TSG sponsored IND and IDE protocols conducted or supported by this Command that lack appropriate administrative processes and procedures established and have not been monitored in accordance with 21 CFR 312, Subpart D.

3. The DCSRCQ has been directed to establish and manage a Regulatory Affairs Division to oversee, direct, and/or conduct regulatory compliance monitoring and to serve as the TSG Sponsor's Representative for this Command in all Regulatory Compliance issues related to the FDA regulated products. All headquarters elements and subordinate commands are directed to support the DCSRCQ in establishing and performing this added mission.

Russ Zajtchuk

RUSS ZAJTCHUK
Brigadier General, MC
Commanding

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